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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,775	07/19/2001	Susan Schiavi	GZ 2065.23	2672

7590 10/01/2002

Antoinette F. Konski
McCutchen, Doyle, Brown & Enersen, LLP
18th Floor
Three Embarcadero Center
San Francisco, CA 94111

EXAMINER

GIBBS, TERRA C

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 10/01/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/909,775	SCHIAVI ET AL.	
	Examiner	Art Unit	
	Terra Gibbs	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, drawn to a method of modulating phosphate homeostasis in a subject comprising altering the activity of a polypeptide encoded by FRP-4, classifiable in class 514, subclass 2.
- II. Claim 4, drawn to a method of modulating renal phosphate transport in a subject comprising altering the activity of a polypeptide encoded by FRP-4, classifiable in class 514, subclass 2.
- III. Claim 5, drawn to a method of reducing phosphate re-absorption in a subject comprising delivering a FRP-4 protein, classifiable in class 514, subclass 2.
- IV. Claim 6, drawn to a method of reducing phosphate re-absorption in a subject comprising delivering a polynucleotide encoding a FRP-4 protein, classifiable in class 514, subclass 44.
- V. Claims 7-14, drawn to methods of screening for candidate therapeutic agents that modulate the expression and biological activity of FRP-4, classifiable in 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I-II are unrelated, each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

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In the instant case the different inventions are drawn to a method of modulating phosphate homeostasis in a subject comprising altering the activity of a polypeptide encoded by FRP-4; and a method of modulating renal phosphate transport in a subject comprising altering the activity of a polypeptide encoded by FRP-4, such that each different invention requires materials and method steps, technologies and search of a body of prior art, that are distinctly different from those required for each of the others such that each different invention would require a separate classification search. For example a method of modulating phosphate homeostasis can occur in, the liver, for example, which is materially different than a method of modulating *renal* phosphate transport.

Inventions of Groups I-IV are unrelated, each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods of modulating phosphate homeostasis, modulating renal phosphate transport and reducing phosphate re-absorption, such that each different invention requires materials and method steps, technologies and search of a body of prior art, that are distinctly different from those required for each of the others such that each different invention would require a separate classification search. For example, the methods of modulating phosphate homeostasis and modulating renal phosphate transport of Groups I and II do not have to necessarily have to include the method of reducing phosphate re-absorption of Groups III and IV.

Inventions of Groups III and IV are unrelated, each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have

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different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method of reducing phosphate re-absorption in a subject comprising delivering a FRP-4 protein; and a method of reducing phosphate re-absorption in a subject comprising delivering a polynucleotide encoding a FRP-4 protein, such that each different invention requires materials and method steps, technologies and search of a body of prior art, that are distinctly different from those required for each of the others such that each different invention would require a separate classification search. These inventions are not disclosed as capable of use together and are independent and distinct because the protein of Group III and the polynucleotide encoding FRP-4 of Group IV have different molecular structures that result in different functions and effects each from the other.

Inventions of Groups I-IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products from the methods of screening for candidate therapeutic agents that modulate the expression and biological activity of FRP-4 of Group V can be used as hybridization probes/proteins, which is a materially different process than the method of modulating phosphate homeostasis of Group I; which is a materially different process than the method of modulating renal phosphate transport in a subject comprising altering the activity of a polypeptide encoded by FRP-4 of Group II; which is a materially different process than the method of reducing phosphate re-absorption of Groups III and IV.

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Claims 8, 10, 12 and 14 are directed to the following patentably distinct species of the claimed invention: (A) a Polypeptide; (B) a Polynucleotide; (C) a Ribozyme (D) a Small Organic Molecule.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, there are no generic claims.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and have acquired a separate

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status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

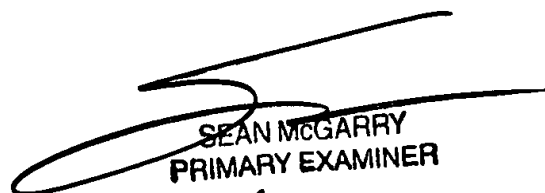
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is (703) 306-3221.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-8693 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

tcg
September 30, 2002


SEAN MCGARRY
PRIMARY EXAMINER
1635